

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

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IN RE ETHICON, INC., PELVIC REPAIR	:
SYSTEM PRODUCTS LIABILITY	:
LITIGATION	:
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This Document Applies To All Actions	:
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CIVIL ACTION NO. 2:12-md-02327

MDL No. 2327

Judge Joseph R. Goodwin

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**PLAINTIFFS' STEERING COMMITTEE'S MOTION AND INCORPORATED
MEMORANDUM IN SUPPORT OF THE PSC'S MOTION TO
COMPEL PRODUCTION OF SALES REPRESENTATIVE FILES**

Summary of Argument

The files of sales representatives are, in some respects, the key documents in any medical device or pharmaceutical litigation. And that is not just because of what they disclose about communications with bellwether case physicians. Rather, the files reveal what the company, as a whole, knew, when the company knew it, what the company did in response and what the company's state of mind was. The detailer's¹ "call notes" (the notes summarizing visits with physicians) are made contemporaneously by the employees themselves and thus lack the sanitization that often accompanies corporate minutes generated after the fact and with an eye toward future public scrutiny.² When a doctor (including a non-bellwether doctor) complains about an adverse event (a complaint triggering the company's duty to notify the FDA), the complaint would obviously appear

¹ “Detailers” is a term of art used by pharmaceutical and medical device companies to describe the employees who hawk the company’s wares to physicians.

Indeed, Ethicon trains its employees not to put “product claims” in emails and to “[b]e very cognizant of what you are communicating electronically as any and all forms of communications can be discoverable in a court of law.” Therefore, what sales representatives write in their own personal notes about the content of their communications with physicians is very likely to much more accurately describe their communications with physicians than any other source of information.

in the call notes. When a detailer downplays adverse risk information, overstates favorable benefit information or promotes a product for an off-label use, these acts – so relevant to plaintiff’s claims of failure to adequately warn, fraud and entitlement to punitive damages – should be reflected in the call notes. Moreover, the detailer’s files contain so much more than just call notes, such as training materials and additional product information. Indeed, in this case, there is evidence in this case that in order to save money, Ethicon instructed its detailers (who are not physicians), to actually train physicians on implantation techniques using a short video of the procedure. Given this evidence, Defendant’s oft-repeated suggestion that plaintiffs need only peruse the files of sales representatives calling on physicians involved in bellwether cases is not only naïve but overtly disingenuous. Ignoring for a moment that defendant has lost, misplaced, destroyed or otherwise disposed of the files of bellwether sales representatives (e.g., at least 99 percent of the documents of one are inexplicably missing), defendant’s proposal should still fall on deaf ears. First, the files of a broader cross-section of detailers may be essential to establish a company policy, something plaintiffs arguably must do to meet their burden of proving negligence, failure to properly train, fraud and other causes of action. Make no mistake: if something supportive of plaintiff’s claims – something adverse to defendant’s public position – appears in a single rep’s file, defendant will holler, “Renegade sales rep!” and throw its own employee (or ex-employee) under the bus, as pharmaceutical and medical device giants have done in every litigation to date. “The detailer was never authorized to make such a representation,” defendant will claim, hence defendant should not be held accountable for the bad act. But the files of other “non-bellwether” sales reps will reveal that these representations were anything but a

“renegade” act. They were, in fact, the norm -- part of a concerted company policy to mislead physicians and downplay risks. These “other” files thus may be critical to plaintiffs meeting their burden of proof. No amount of so-called “burden of production” rhetoric can justify denying plaintiffs the opportunity to prove their case.

Nevertheless, the PSC has bent over backward to do what it can to ease the purported burden of production on defendant. Initially, defendant’s claim that there is no central recordkeeping of detailer documents is difficult to fathom since defendant must evaluate its countless sales employees’ performances. Defendant is, after all, a business. But assuming *arguendo* that defendant employs no means of evaluating its sales representatives’ performance by keeping track of any of its sales employees’ files, plaintiffs have still offered defendant an enviable compromise. In particular, plaintiffs have proposed production of the files of only 100 sales reps a month – files from detailers whom plaintiffs will choose at random. All will be detailers who called on doctors treating plaintiffs whose cases are already before this Court. Based on what this production reveals, either party could subsequently move the Court, at any time, to expand or lessen the production.³ Defendant, determined to prevent plaintiffs from proving the companywide policy which may ultimately be so important to their claims, has rejected this proposal. Hence, the instant motion is necessary.

³ Ex. 1 (Plaintiff’s Proposed Stipulation).

Plaintiffs even reluctantly offered reducing this number to 50 files a month, even though that will substantially prolong this litigation. The bottom line is that plaintiffs must get this data, and if we have to get it slowly, we will. Defendant asked plaintiffs to reduce their monthly request. Defendant has yet to respond to the offer. And in fairness, these requests have been whirlwind. Plaintiffs make no claim of dilatory conduct here. We just need the data!

ARGUMENT AND AUTHORITY

In the interest of brevity, plaintiffs will not inundate the Court with the case law describing how broad the scope of discovery is in the federal system, how there are legitimate reasons to restrict it, and the like. Instead, plaintiffs will show that the discovery sought is essential to their claims and the burden on defendant can be minimized (and, in any event, should not justify denial of such vital data).

I. A Production Order Extending Beyond Bellwether Cases Is Essential to Ensure Plaintiffs Receive at Least a Modicum of Sales Rep Documents.

The PSC is reluctant to posit this argument first as we believe the plaintiffs in this litigation are entitled to sales rep files for those reps who called upon their implanters beyond those involving bellwether plaintiffs. After all, each plaintiff is entitled to her own day in Court. But the bottom line is it is now clear that Ethicon, because it has failed to preserve documents in contravention of its own litigation hold policies, is unable even to make a smattering production *in the bellwether cases themselves*, making broader production mandatory. Hence, this argument is the clearest and simplest (though not necessarily the most substantive) justification for securing additional files.

By way of example only, the detailer in the first bellwether trial, Carolyn Lewis, Paul Courts had the sum total of 35 documents in his “custodial file” when defendant ultimately produced the “file” to the plaintiff in that case pursuant to its obligations in the Defendant’s Fact Sheet. Yet, the “custodial files” of other witnesses revealed that Mr. Courts had been copied on many more documents. When confronted with these facts during his deposition – as well as with the inadequacy of his own file – Mr. Courts admitted under oath that there should have been thousands of additional pages produced.

He also made clear that he turned over everything – far more than was produced – to his boss, in response to this Court’s litigation preservation order.⁴

Indeed, the spoliation of Mr. Courts’ file is no way an isolated event. Other sales representatives have testified similarly, yet critical documents have gone missing. In fact, the destruction of documents after litigation hold letters were in effect goes all the way up to the president of Ethicon, Renee Selman, who was also deposed. In Ms. Selman’s case, Ethicon has admitted up front, in two separate letters preceding the scheduled deposition, that the custodial file was wholly inadequate, even to the point of suggesting the cancellation of the deposition because of the lack of documents. In fact, the production was so inadequate that Ethicon was forced to admit that defendant’s employees were not following the Court’s preservation order.⁵

This motion will not address the mindset (whether one of intent or negligence) of defendant’s extensive destruction of evidence. That will be the subject of future briefing. For now, whether defendant lost or tossed its bellwether sales representative files is immaterial. What is important is that plaintiffs require more than 35 pages out of thousands from bellwether reps to establish their claims. Thus, plaintiffs must receive whatever defendant can produce, not just a few pages relating to trial-set cases.

II. A Production Order Extending Beyond Bellwether Cases Is Essential to Ensure Plaintiffs Can Meet Their Burden of Proving Corporate, as Opposed to Mere Employee, Culpability.

Plaintiffs have pleaded, and are entitled to prove in each case, their entitlement to punitive damages. While the law varies from state to state, we can all agree this

⁴ Deposition Excerpts of Paul Courts, July 16, 2013 (Ex. 2) at 388:13-391:8.

⁵ Correspondence from Christy Jones to Bryan Aylstock, Apr. 2, 2013, June, 13, 2013 (Exs.3, 4).

entitlement generally requires plaintiffs to prove at least gross negligence and, in many states, reckless disregard or some variant thereof. In some states, though, the requirement not only relates to culpability but who is culpable. In Texas (the residence of Carolyn Lewis), for instance, a litigant must prove that the wrongful conduct was part of a corporate policy.

In virtually every litigation involving drug or medical device companies, the response to sales call notes revealing misstatements, over-promotion and the like is always the same – “He acted on his own; she is a renegade rep; she wanted a bonus; we didn’t authorize this.” In those litigations where more than bellwether case call notes are required, these claims ring hollow because the evidence reveals that these bad acts are universal and part of a company policy. Defendant hopes to prevent such proof from coming to light by limiting production to a few people they can individually impugn. This, the Court should not countenance.

III. A Production Order Extending Beyond Bellwether Cases Is Essential to Prove a Pattern or Practice of Misconduct.

Not only does such evidence assist in proving the existence of a corporate policy, it is also important in proving a pattern or practice, which is also important to proving Plaintiffs’ punitive damages claims. *See, e.g., Watkins v. Lundell*, 169 F.3d 540, 546 (8th Cir.), *cert. denied*, 528 U.S. 928 (1999) (evidence of a “pattern, practice or scheme characterized by fraud or deceit” is evidence of reprehensibility to be considered in evaluating punitive damages claim).

Furthermore, evidence of a pattern or practice of over-promoting the product is essential to overcoming defendant’s learned intermediary” defense. Courts have held that a manufacturer cannot hide behind this defense, even if the manufacturer provided

adequate warnings, if the manufacturer engaged in a pattern or practice of deceptive marketing that overwhelmed the effect of the warnings on physician knowledge and beliefs. *See, e.g., Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (over-promotion may erode the effectiveness of otherwise adequate warnings); *Whitley v. Cubberly*, 210 S.E.2d 289, 291-92 (N.C. App. 1974) (over-promotion to medical community in general as well as to individual physician is relevant). Defendant has pled the learned intermediary defense affirmatively in this litigation but now seeks to limit the Plaintiffs' ability to combat that defense.

In *Incollingo v. Ewing*, the plaintiff sued the manufacturer of a dangerous drug and the two physicians prescribing it. One physician testified he considered himself adequately warned of the drug's dangers; the other testified to the converse. The court held that evidence regarding the manufacturers' general practice of overselling the drug throughout the medical field supported the jury's finding that the warnings were inadequate in that they constituted evidence that would tend to confirm the latter doctor's testimony and dispute the former doctor's claim.

Plaintiffs were allowed over objection to introduce, by expert witnesses, evidence directed to showing a failure to warn the medical profession. This consisted of the custom and practice of the manufacturer, Parke, Davis, in "overpromoting" its product, primarily through the use of detail men who minimized the dangers of the drug while emphasizing its effectiveness, wide acceptance and use, and lack of certain objectionable side effects associated with other drugs. The question is whether this evidence was properly admitted.

* * *

As a practical matter, it would have been difficult, if not impossible, to show how the promotional efforts of the manufacturer bore on the judgments of these co-defendants without demonstrating that the efforts were directed to the entire class or group of which they were members.

282 A.2d 206, 221-222 (Pa. 1971). By the same token, Plaintiffs should be permitted to show how defendant's pattern and practice of over-selling its product misled physicians as a group into believing the product was safe. Plaintiffs cannot be compelled to accept the testimony of their implanting physicians, many of whom are paid consultants or spokespeople for the defendants, and all of whom stand to gain financially by continuing to implant women with these products.

IV. A Production Order Extending Beyond Bellwether Cases Is Essential to Establish Defendant's Knowledge of Adverse Events Putting Them on Notice of Either The Need for a Stronger Warning or the Need for an Application for Such to the FDA.

What defendant knew about defects in its products and when defendant gained that knowledge lie at the heart of Plaintiffs' causes of action. The "notebooks" and call notes possessed by defendant's sales agents will possess such information. By defendant's own admission their agents recorded information the physicians provided regarding adverse events, concerns or complaints about the product, in addition to information regarding any response the sales agent made.

Defendant's actual knowledge that its products were ineffective or detrimental are important components of Plaintiffs' negligence, fraud and misrepresentation claims. *See, e.g., Hermes v. Pfizer, Inc.*, 848 F.2d 66, 68 (5th Cir. 1988); *Golod v. Hoffman-LaRoche*, 964 F. Supp. 841, 855 (S.D.N.Y. 1997) (both holding adverse events, particularly recurring ones, may trigger a duty to warn). Undoubtedly, the vast majority of information defendant possessed regarding the inefficacy and dangers of its product came from physicians who did not treat MDL plaintiffs.

V. A Production Order Extending Beyond Bellwether Cases is Essential to Establishing Defendant's Negligent Training of Physicians.

Testimony and documents produced in this case reveal that in order to save money, sales representatives, although not physicians and many of whom have no medical training, were told to train physicians on the use of the TVT devices using a CD-Rom of the procedure. In fact, because Ethicon had rejected a request for additional professional education funding, Ethicon sales representatives were told “They can sit down with [the average obgyns] for 45 minutes, go through the procedure (cd rom and leaflets), discuss the anatomy and use a sample of the [pelvic floor] model.”⁶ Defendants will no doubt claim that this is not really company policy and it trained physicians appropriately on the proper use of its products. But this claim can be refuted by the information contained in the files of the sales representatives, including the notes of these training sessions, and copies of this cd-rom and leaflets provided to the physicians.

CONCLUSION

For any of the foregoing reasons, plaintiffs respectfully request that the Court order defendant to (a) produce all custodial files of sales representatives calling on physicians treating bellwether plaintiffs, as agreed to already, (b) begin a rolling product of the custodial files of a minimum of 100 sales representatives (or 50, as explained above) per month, with plaintiffs choosing the representatives from among those already involved in cases in this litigation, and (c) to otherwise fully and completely respond to Requests for Production numbers 98-104, 106, 108, 109-110. Plaintiffs further request all other relief to which they are entitled.

⁶ See Ex. 5, Parisi deposition 6-6-2013 at 215; and Ex. 6, Depo Ex. T-1065 (to be provided *in camera*)

Dated: August 15, 2013

Respectfully submitted,

/s/ D. Renee Baggett

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CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2013, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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